ADVISORY COUNCIL ON SCIENCE AND TECHNOLOGY

A Report on Medical Research and Health

CABINET OFFICE

OFFICE OF PUBLIC SERVICE AND SCIENCE

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ADVISORY COUNCIL ON SCIENCE AND TECHNOLOGY (ACOST)

Terms of reference:

To advise the Government on:

- priorities for science and technology in the United Kingdom;

- the application of science and technology, developed in the United Kingdom and elsewhere, for the benefit of both the public and private sectors in accordance with national needs;

- the co-ordination, in collaboration with Departmental Advisory Bodies, of science and technology activities;

- the nature and extent of United Kingdom participation in international collaboration in science and technology.

To publish reports as appropriate.

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FOREWORD

Dr Peter Doyle CBE, Chairman of the ACOST Medical Research and Health Committee

When I was invited to chair the ACOST Medical Research and Health Committee, I readily accepted, for a number of reasons:

Firstly, because advances in medical research, particularly but not exclusively in molecular biology, have opened up exciting possibilities for both novel treatments and significant improvements over present treatment.

Secondly, there is a growing national concern to encourage innovation and improve technology transfer, and I strongly believe that there is considerable scope for expediting the way advances in medical research are brought to the marketplace.

Thirdly, health care represents one of Britain's successful international industries; we therefore ought to do everything we can to build on that success.

All of us, out of either a natural self-interest or public interest, are concerned that the UK maintains an effective health care system, backed up by high quality research. For this reason, medical research and its contribution to improved health care are a constant focus for both political and media attention. More than in any other field, therefore, the public is aware that there have been significant advances in technology which have increased the scope of treatments possible.

This is effectively captured by the Secretary of the Medical Research Council (MRC) who said in his foreword to the 1991 MRC Corporate Plan 'The last 20 years have seen remarkable advances in the biological sciences. The opportunities to apply these to the prevention and treatment of disease are unprecedented and still further progress will follow if the momentum in basic research is sustained'.

Worthwhile advances also have occurred in other areas of science, in a way that has led to better drugs and diagnostic agents, improved surgical procedures and non-invasive ways of detecting health problems.

Understandably, the public's growing health awareness and treatment expectations, combined with changes in the age structure of the UK population, has generated a continuous pressure on health service resources. Against that background, it is in

everyone's interest that proven advances in medical research are adopted rapidly, and disseminated widely, in order to replace less effective treatments or procedures.

How that process, from research into widespread use, can be optimised is the subject of the present report, which sets out to cover the area in a way that avoids overlap with related studies, but rather seeks to complement them.

Over the last few years, following the White Paper *Working for Patients* and the 1988 Report of the House of Lords Select Committee on Science and Technology *Priorities in Medical Research*, there have been substantial reforms in the organisation and management of the National Health Service (NHS).

Of particular importance to the present study has been the appointment of Professor Michael Peckham as Director of Research and Development (R&D) at the Department of Health (DH). Through him, the creation of an NHS R&D strategy, and an infrastructure to give effect to that strategy, will ensure that R&D becomes an integral part of health care, and that decisions and resource deployment are knowledge-based.

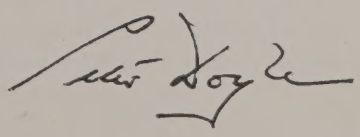
More recently, the White Paper *The Health of the Nation* has set out a health strategy with priority areas for attention for England, paralleling comparable steps in Scotland, Wales and Northern Ireland. A key aspect of this publication was the concentration on health promotion as well as health care, and the setting of clear and stretching targets.

Current NHS reforms separate the financing of health care from its provision. This has resulted in an increased emphasis on health economics, the cost effectiveness of treatment and the need for technology assessment which will have implications for medical and health research.

In particular, there is growing scrutiny of the process by which advances in R&D are translated into improved patient care in a cost effective way. It is this aspect which has been at the centre of the study carried out by ACOST's Medical Research and Health Committee.

Given the breadth of the field, the Committee had to be selective in what it chose to study; for example, dental health and the specific question of education and training were omitted. However, through its five task forces, the Committee was able to reach a number of general, and specific, recommendations for action.

I believe this study is both opportune and timely. It comes shortly after *The Health of the Nation* and at a point where a crucial mechanism for implementing its recommendations - the regional infrastructure to support the NHS R&D strategy - is virtually complete.



TERMS OF REFERENCE

Objective

To identify how advances in science and technology can be used to provide better health in the most cost-effective way.

Terms of reference

1 To study selected medical and health advances with particular reference to how effectively such advances have been put into practice and the extent to which they have contributed to cost- effective treatment and the delivery of health care.

2 To suggest how the exploitation of the results of both UK and non-UK medical and health R&D programmes could be improved, including identifying ways of improving technology transfer links between the NHS, industry and the science base.

EXECUTIVE SUMMARY

Introduction

Advances in the biological and physical sciences have led to an unprecedented flow of opportunities to develop new medical technologies and to improve health care. The UK is well placed to take advantage of these developments.

British medical and health research is widely recognised as world class. The UK based pharmaceutical industries in particular have capitalised on this strong research base and are major contributors to the nation's balance of trade. The rapidly rising world wide demand for health care offers further substantial opportunities. However it is an increasingly competitive market. It is essential, therefore, that the exploitation of science through innovation in medical and health care technologies is strongly encouraged and developed in the UK. The report has sought to identify constraints and opportunities for improvement in the transfer of technology in the medical and health care fields.

Scientific advances in the medical and health care fields have been paralleled by a corresponding increase in the public awareness of health matters, the demand for treatment and the expectations placed on health services both nationally and internationally. Similarly, changes in demography - most notably the ageing of the population - increasingly place particular demands on the delivery of health care. It is necessary therefore to ensure that the best possible use is made of the available resources for the benefit of patients. As a result of the work of five Task Forces which looked at pharmaceuticals, gene therapy and transplantation, surgery, medical devices and screening, the report identifies a number of ways in which this might be done through technology assessment and evaluation.

The Innovation Process

The report identifies the existence of a development gap in the transfer of advances in research to the early development stages for new medical and health care treatments. This development gap, which exists between the research laboratory and industrial exploitation, is a particular difficulty in the UK. We recommend:

- the creation of a *MEDILINK* programme to support the exploitation of research allied to medical and health care;

- improved training for researchers in the importance of intellectual property rights;

- that through the current international discussions on the harmonisation of patent laws, the National and European Patent Offices establish a twelve month period of grace for the filing of a patent following the publication of research results.

Health Technology Assessment

We strongly support the steps being taken by the Department of Health to promote health technology assessment. Such assessment programmes should be centrally determined and strategically driven. It is essential, too, that the assessment procedures incorporate effective data analysis systems including methodologies to assess economic and quality of life data. We recommend that:

- the National Health Service requires all new medical devices or novel applications of existing devices to be developed only under controlled conditions;

- the Health Departments establish a Committee on the Safety and Efficacy of Procedures, with which novel surgical procedures would be registered.

Implementation

No matter how effectively medical advances are developed and assessed it is only by the active take-up and widespread use of such validated procedures that patients will benefit. Currently the introduction of new developments in health care in the UK can be a haphazard process. To be effective an implementation strategy should seek to influence research scientists, clinicians, health service managers, patients, policy makers and industry. We recommend that:

- the NHS introduces training programmes in Good Clinical Practice for Clinicians and Scientists involved in the design, execution and reporting of clinical research trials;

- the NHS Supplies Authority improves the rate and quality of feedback on product performance to suppliers;

- the Health Departments and health care industries develop and agree common and validated methodologies for the assessment of economic and quality of life data;

- groups within the health service be identified to assume responsibility for receiving and assessing technology assessment data;

- the NHS, through its Regional Directors, establishes appropriate implementation and monitoring programmes for the adoption and uptake of new validated procedures.

For some areas of medicine the appropriate technologies are available yet other constraints inhibit their widespread and cost-effective use. One striking example of this is in organ transplants where a continuing shortage of organs prevents the full benefits to patients being realised. We recommend:

- that Health Departments introduce an opt-out system for organ donation in an attempt to overcome the chronic shortfall of organs for transplant.

We have examined the role of public health screening in preventive medicine. The present system frequently lacks coordination and the essential rigour of quantitative analysis. The strategic importance of a focus on preventive medicine was confirmed in the 1991 White Paper *The Health of the Nation*. We recommend:

- that the NHS establishes a major initiative to ensure that screening research is used to direct national policy formulation and that high quality screening programmes are available throughout the NHS.

The report addresses each of our recommendations to identified groups for action. We plan to follow up the report with a review of progress which we intend should be carried out within 12 months of receiving the Government response.

1 INTRODUCTION

1.1 The UK has a strong and widely recognised tradition in medicine and medical research which owes much to the quality of its teaching hospitals, academic and research institutes, and the commitment from scientists and clinicians to carry out world class medical and health research (see note 1 and 2).

There can be little doubt that advances in medicine continue to improve the treatment of ill health and increasingly contribute to disease prevention. For example, it was investment in basic biomedical research which led to the discovery of the beta-lactam antibiotics, penicillins and cephalosporins, which have made a major contribution to the control of bacterial infections.

More recently the invention of monoclonal antibodies has opened up further unique approaches to the control of infection, and through their ability to target specific cells, novel ways of treating major cancers.

Further progress in the understanding and treatment of *inter alia* cardiovascular disease, cancer, arthritis, asthma and genetic disorders, will make a major impact in improving health and health care. Thus new techniques in molecular genetics, immunology, and biochemistry, are producing fundamental information on carcinogenesis and the make up of the nervous system, in a way which will lead to dramatic improvements in the treatment of such problems as lung and colorectal cancer, dementia, stroke, and multiple sclerosis.

1.2 As a result of advances in molecular and cell biology there has been an explosion in research, and unparalleled opportunities to tackle diseases.

The pace of progress, from the discovery of the double-stranded helical structure of deoxyribonucleic acid (DNA) in 1953 to recombinant DNA techniques has been rapid, particularly through the late 1980s. This has led towards the ambitious international project to map the human genome. A major advance has been the molecular diagnosis of genetic disorders, and their potential treatment by gene therapy.

Physics and engineering too have contributed to major advances in many other areas of medicine, for example, endoscopy, surgical instrumentation, and particularly to innovations in non-invasive techniques. Thus, medical imaging through ultrasound, thermal imaging, three-dimensional x-ray scanning (computerised tomography), and whole body scanning by magnetic resonance imaging (MRI), are now routinely used.

This impressive progress has been complemented by the considerable research achievements in the pharmaceutical and medical equipment sectors of health care which, together, generate over £3bn of exports and create a positive trade balance of around £1.2bn.

The healthcare industry, therefore, is justifiably regarded as amongst the UK's most successful industries.

1.3 In parallel with these advances there has been a rise in the public's health awareness and treatment expectations which has created demand for improved and effective therapies. These expectations, and the effects of demographic changes in the UK, have led to a relentless upward pressure on the cost of health care, which will persist in the 1990s and beyond.

Although as Table 1 shows, there has been some levelling off recently, in the 1970s and early 1980s expenditure on health rose faster than the growth in the economy in almost all countries in the Organisation for Economic Co-operation and Development (OECD) (note 3).

There are two main reasons for this increased expenditure. Firstly, in all these countries the proportion of old people, the major consumers of health care is rising. Secondly, technical and pharmaceutical innovations in health care have led to a real increase in demand for better quality therapeutic agents, novel treatments such as joint replacement, and organ transplants.

Table 1 **Total health expenditure as a percentage of gross domestic product (GDP), per capita health expenditure and per capita GDP (OECD data).**

				1990$ per capita	
	1990	1989	1985	health expenditure	GDP
Belgium	7.4	7.4	7.4	1087	14,672
Denmark	6.2	6.4	6.3	963	15,452
France	8.9	8.8	8.5	1379	15,568
Germany	8.1	8.2	8.7	1287	15,943
Japan	6.5	6.7	6.5	1113	17,019
Netherlands	8.0	8.1	8.0	1182	14,609
Sweden	8.7	8.7	8.8	1421	16,320
United Kingdom	6.1	5.8	5.8	909	14,907
United States	12.4	11.7	10.7	2566	20,774

Health expenditure measures are commonly expressed as the amount per person as a fraction of gross domestic product (GDP). Table I above details the health expenditure in selected European countries, Japan and the United States as a percentage of GDP. It also lists the per capita health expenditure and per capita GDP in US dollars for 1990. In interpreting international differences, factors such as the expectations and demands of patients, salaries of health professionals relative to the rest of the population, and the overall efficiency of the system have to be taken into account. The figures do however provide some guidance on changes within and between countries.

1.4 In the UK, the NHS is the major purchaser and consumer of medical and health care technologies, and the main beneficiary of medical and health R&D achievements. In recognition of this, the House of Lords Select Committee on Science and Technology investigated how priorities for medical research were set. In 1988 they produced a detailed and constructive report with a number of key recommendations. One of these recommendations led to the appointment of a Director of R&D at the DH with responsibility for setting R&D priorities.

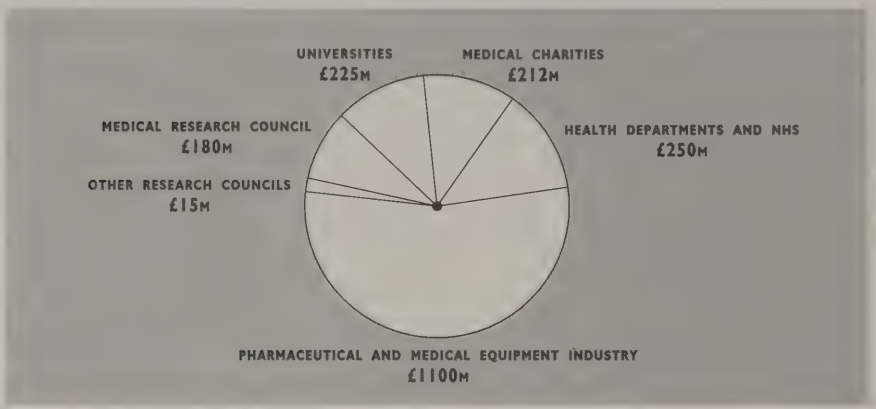
The subsequent publication of *Research for Health* an NHS R&D strategy for England is a major step forward, and together with the mechanisms developed in the rest of the UK, if adequately resourced, should provide the means of implementing some of the principal recommendations in this report.

1.5 The total investment in medical and related research is diverse. Thus Figure 1 shows the approximate distribution of the £2 bn spent in the UK each year on medical and related R&D. The Government spends over £650m, of which the NHS share is around £225m.

Funding of R&D by the medical charities is significant at around £210m, and will increase markedly with the Wellcome Trust's plans to double its spending on medical research after selling a substantial proportion of its share holding in Wellcome plc.

There is, of course, also sizeable industrial activity in medical and health R&D with investment by the pharmaceutical companies in the UK of over £1bn.

Figure 1 **UK investment in medical and related R&D in 1991 (DH data)**



1.6 Through consistent investment in basic research, the medically related sciences, stimulated by advances in molecular biology and electronics, are at a more exciting stage now than at any point in history, and the opportunities for innovation in health care are considerable and diverse.

Strategies will therefore need to be developed to ensure that such innovations result in clinically effective and cost-effective care and treatment of patients. The study of medical research and health, and how it impinges on health care, is a topic of international importance, and has been the subject of many past studies both nationally and internationally. We have therefore not attempted to provide a comprehensive analysis of the subject but rather sought to identify certain areas which highlight the issues, and lead to both general and specific recommendations.

1.7 With this in mind, and to aid its deliberations, the ACOST Committee set up five task forces, each chaired by a Committee member. **These task forces deliberately focused on a number of carefully selected topics: namely pharmaceuticals, gene therapy and transplantation, surgery, medical devices and screening.**

Their reports were a major input into the Committee's work. Another key source of information for the Committee and task forces was the responses to an inquiry note sent out to over one hundred individuals and organisations inviting comments on the medical innovation processes.

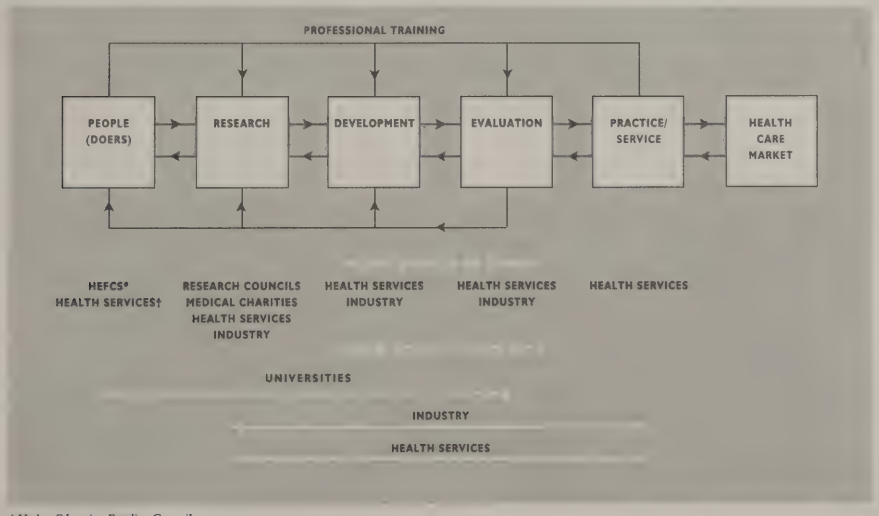
In addition, to gain an international perspective some Committee members also visited Washington, Brussels and Stockholm. These discussions confirmed the Committee's views that national and international concern was focused on developing strategies for technology assessment, disseminating good practice, and reaching a balance between cost effectiveness and patient care.

1.8 A major objective of the Committee has been to identify constraints and scope for improvement in the technology transfer process. In particular how the latter can be achieved in the most cost-effective way.

The following discussion is aimed at illustrating different steps in the progress of a medical advance from early development to use in patient care.

1.9 In view of the work already undertaken and published by the Select Committee of the House of Lords on *Priorities in Medical Research*, the ACOST Committee decided to look beyond the research stage and concentrate on improving the processes of development, evaluation/assessment and dissemination/uptake. However, this is not to suggest that all innovations pass through all these stages in a strictly linear fashion. Thus Figure 2 describes some of the interactive elements involved in the innovation cycle.

Figure 2 **Some interactive elements in innovation**



* Higher Education Funding Council
† Includes health departments and NHS

1.10 Technology transfer is acknowledged to be a complex process in which it is difficult to exaggerate the role of people and their education and training. An adequate supply, appropriate training and good career prospects for research minded clinicians, scientists, and health service researchers, are all crucial to the objective of ensuring cost-effective and efficient technology transfer. Indeed, continuous education and training is essential if maximum benefit is to be achieved from advances in medicine and health. There should be a two way flow of undergraduates, graduates, post graduates, and senior scientists between industry and academia.

The importance of education and training is well recognised, and is reflected by the various groups already tackling these issues. The Committee therefore did not focus on education and training specifically, but addressed such concerns only in the context of the task force studies.

1.11 The following conclusions and recommendations are a result of distilling and condensing the views from the five task forces. However, it has to be recognised that each task force gave somewhat different weight to these recommendations.

2 DEVELOPMENT

Innovation

2.1 Innovation in medicine is a dynamic and inherently iterative process, driven by both science push and demand pull. Successful development, therefore, demands effective interaction between the science base and the health care market.

Thus, the choice for the public is governed by health care professionals who determine the kind and level of the intervention needed. However, the rise in health awareness and treatment expectations, together with the NHS reforms provide the public with more choice and influence.

The complexity of the market is illustrated by the dual role of some clinicians in the innovation process. They are not only the users of new technology, but are also active in its development. This dual role is especially visible in the modifications which occur in surgical practice.

It also exists in device and drug innovation, where the introduction of new products in clinical practice often leads to the unexpected discovery of new indications of use. This is strikingly illustrated by the beta-blockers. Though developed initially for the treatment of angina and cardiac arrhythmias, it was clinical investigation which revealed their ability to lower blood pressure which is now the major use for these products.

The development gap

2.2 One of the key conclusions of the task forces, strongly reinforced by responses from the inquiry note, is that a development gap exists in transferring research findings to early development and prototype stages.

Thus, differences in perception between academia and industry of what constitutes an exploitable invention often leads to misunderstanding and problems, with industry frequently unwilling or unable to provide the necessary support to academia.

The solution is to identify areas of potential and bring the inventor and industrial partner together in an act of collaboration, so that there is a clear strategy, effective management and sufficient funding and expertise to facilitate advances in pharmaceuticals, medical devices, diagnostic agents and advances from newer areas of research such as gene therapy.

2.3 This development gap between research laboratory and industrial exploitation is a particular difficulty in the UK. It exists between the point where further science base funding is inappropriate, but progress has not reached a stage sufficient to justify company investment.

Frustrated inventors contrast British industry's reluctance to pick up technology at an early stage because of the risks involved, with the enthusiasm shown by US and Japanese manufacturers for new product ideas and for their willingness to invest for the longer term.

2.4 In Japan, for example, the Ministry of International Trade and Industry (MITI) provide access to long-term loans which are repayable in part from subsequent income, while in the US, this type of collaboration is actively encouraged by the National Institutes of Health (NIH) through their Cooperative Research and Development Agreement (CRADAs). In addition, a number of US and Japanese companies have set up significant focused research programmes alongside UK universities via research institutes which combine the discipline of an industrial company in directing research with the access to the intellectual capabilities of background R&D within the universities.

2.5 In the UK, the DTI have been involved in the creation of an additional mechanism for technology transfer through the Faraday concept.

In the area of medicine and health, intermediate institutions which can link Higher Education Institutes and teaching hospitals in a way that will assist clinical research to be coupled effectively to industrial product development on a contract basis are to be strongly encouraged.

In this regard, the Centre for Advanced Instrumentation being set up by University College London and the Scientific Instrument Research Association (SIRA) to undertake R&D and pre-production manufacturing, funded by industry, charities and the NHS represents an attractive model.

Other worthwhile DTI technology transfer schemes, some with a focus on small and medium sized companies, are Support for Product Under Research (SPUR), Small Firms Merit Award for Research and Technology (SMART) and LINK. However, none is specific to health care.

In view of the proven success of the health care industry, we believe there is a strong base to build on that success by earmarking specific funds for a health care programme within the existing LINK scheme to facilitate 'towards market' R&D in health care.

2.6 **We recommend that the DTI in collaboration with the health departments create a specific '*MEDILINK*' programme to facilitate the exploitation of selected ideas from academic and research institutes and the NHS.**

ACTION
DTI to introduce a 'MEDILINK' programme within the present LINK scheme.

Exploitation

2.7 Despite the compelling logic and apparent willingness of all parties concerned to become involved in collaborations, their needs are in some ways in conflict, for example, protection of intellectual property versus freedom to publish.

The transfer of intellectual property from Higher Education Institutes (HEIs) to industry is a three stage process comprising the identification of patentable ideas, the protection of these ideas, and their exploitation via licensing or a start-up company.

Though some HEIs have development units to manage their intellectual property, on the whole the system is underdeveloped and under resourced. As a result some academic institutes and health professionals have not identified intellectual property at an early enough stage; thus research findings which could have been developed to benefit patients have not received the investment and support required to develop the idea into a product.

Although the culture in academic institutions is changing, training in the importance and evaluation of intellectual property is required for all biomedical research students.

2.8 **We recommend that the HEIs should, with appropriate organisations including the NHS, MRC, Association of the British Pharmaceutical Industry (ABPI), Association of the British Health-care Industries (ABHI) and the UK patent marketing department, design and provide training for research students and scientists in the importance of the exploitation of research and the value of intellectual property rights (IPR).**

ACTION
HEIs to facilitate design and provide training in the importance of IPR.

2.9 As discussed above, the pressure on scientists to publish their research quickly has restricted the interaction between academia and industry. Ideally, for exploitable science and technology, filing of a patent should precede publication. However, as a safeguard, we strongly support the recent request from the Science and Engineering Research Council (SERC) to DTI, to secure a significant period of grace and a greater coincidence of European and US patent laws, through the discussions on harmonisation.

2.10 **We recommend that the National Patent Office and the European Patent Office initiate legislative changes to allow publication of a discovery with protection of IPR provided a patent is filed within twelve months after publication.**

ACTION
Patent Offices to allow twelve month period of grace.

3 ASSESSMENT AND EVALUATION

Health technology assessment

3.1 The development of medical advances should be seen as an iterative process in which information is collected, validated, disseminated, evaluated and refined. Assessments can thus be made at different times in the cycle.

Technology assessment is not a new concept in medicine, and many clinicians have sought to understand the effects of the interventions they apply. With the development of clinical research, attempts to establish safety and efficacy have become more systematic and scientific, culminating in the development of the randomised clinical trial.

With the exception of pharmaceuticals, demands for proper evaluation, before widespread introduction, have been questioned because it 'stands to reason' that the new techniques will be 'better'. However, the lack of effective assessment and evaluation has prevented some advances being developed, and hindered the replacement of ineffective and outdated techniques or procedures.

3.2 Stimulated by concern about the quality, effectiveness, and escalating cost of health care in recent years, the scope of technology assessments has broadened. The latter now encompass the measurement of effectiveness, consideration of the quality of life and patients' preferences, and especially the evaluation of costs and benefits.

The key purpose for technology assessment is to help in decision making processes. However, there is currently a lack of overall management of assessment activities as well as a lack of recognition of the importance of medical technology assessment. For example, many health professionals are unwilling to participate in, or encourage, clinical trials, while NHS managers are not pressing sufficiently for assessment data.

Widespread interest in technology assessment has flourished recently, and we are particularly encouraged by, and strongly support, the steps being taken by the DH R&D division to promote health technology assessment, through the establishment of the Cochrane Centre at Oxford, and the subsequent publication of a paper on *Assessing the Effect of Health Technologies* by the Department of Health.

It is essential that any health technology assessment programme is centrally determined and strategically driven. Provided that units with critical mass are established regionally, the programme could then be implemented through regional R&D directors who after collectively selecting priorities would take the lead on different spheres of medicine and health.

3.3 In parallel with demands for more effective evaluation, there have been concerns that development and diffusion will be inhibited. Although these concerns might be justified to some extent, the overall long-term benefits to patients outweigh possible short-term delays in diffusion which would be minimised by effective communication between the assessors and the decision makers.

Adequate resources must be provided to support the DH R&D division's plan to introduce an Information Systems Strategy (ISS). The system will underpin the NHS R&D programme, not only supplying information about planned and ongoing R&D of relevance to the NHS but also disseminating the results of research.

3.4 If a novel development is to be promoted for general use it is therefore essential that it should undergo scientific assessment including evaluation of safety, efficacy and outcomes, in the short and long-term, comparison with existing options, cost-effectiveness and indications for use.

This would include using protocols where optimal assessment can take place to ensure that the procedures are shown to be medically acceptable for general use. Such an assessment procedure should also involve assessment of the cost-effectiveness of the new device or novel procedure. Those which offered significant patient benefits should then be given priority funding from the Health Departments to facilitate their integration into the NHS. Thus there is a need for dedicated facilities around an associated skills base to develop methodologies and carry out these assessments in a systematic way. Also the lack of an effective information system has inhibited the gathering and evaluation of both national and international assessment data. The DH initiative to fund the Cochrane Centre at Oxford is an important first step.

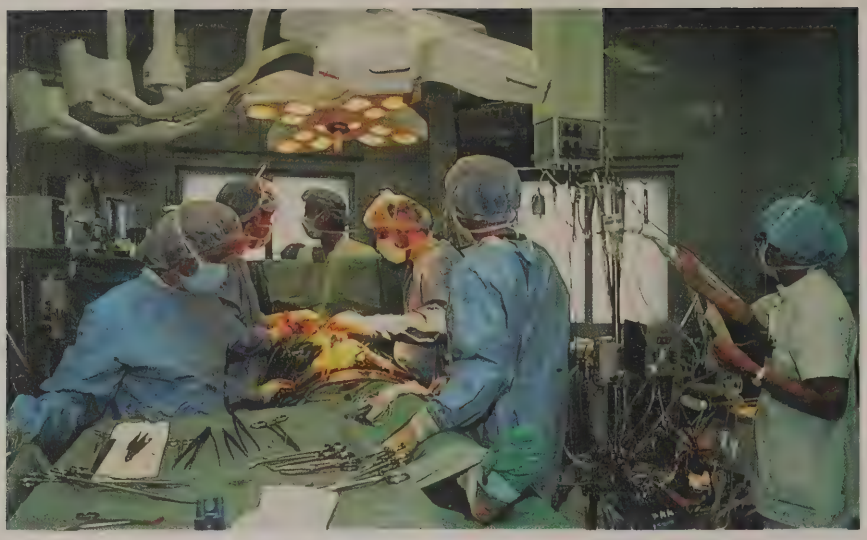
3.5 **We recommend that the NHS require all new medical devices or novel applications of existing devices to be developed only under controlled conditions, and linked to validated data collection and analysis systems in a way that will facilitate effective dissemination of results.**

ACTION
NHS to require all new devices or novel applications to be developed, only under controlled conditions and data collected in a timely and systematic way.

Surgical procedures

3.6 Advances in anaesthesia, antibiotics and fibreoptics have resulted in a revolution in surgical practice. The pace of change has highlighted the need for surgeons, managers and policy makers to develop strategies to evaluate and control the introduction of new technologies. In attempting to ensure the introduction and use of best practice, the Committee paid particular attention to the development of minimal access surgery.

3.7 The available evidence indicates that although it is a relatively new therapeutic technique, minimal access surgery can offer real benefits on the cost and quality of care in an increasing range of applications. Its development and adoption has in many cases been rapid although often haphazard, resulting in some cases in uncritical take up and uncoordinated introduction with a less than effective return to the NHS. The small though increasing number of negative reports (mainly concerned with overuse of the procedures) emphasises the need for early action to introduce formal assessment procedures. Protocols should be established so that optimal assessment can take place to ensure that procedures are medically acceptable for general use.



3.8 **We recommend that the health departments establish a committee on safety and efficacy of procedures to review and register novel surgical procedures.**

ACTION
The Health Departments to establish a Committee on Safety and Efficacy of Procedures.

Health economics

3.9 Some medical advances, for example pharmaceuticals, may generate economic benefits which accrue to areas of the NHS or other Government Departments, for example the local authority social services, other than the one which directly bears the cost of their supply.

Understanding of economic and quality of life assessments of treatments or technologies within the NHS is limited. This impedes the communication of information between providers and potential users of economic evaluation data. The existence of budget boundaries within the NHS also constrains the capacity of the service to respond to these data.

3.10 The growing importance of health economics is reflected in its increasingly high profile and the number of units dedicated to providing economic data. However, further R&D is necessary to create generally accessible and validated methodologies.

There is a lack of standardisation in the production of health economic and quality of life data. Also the absence of any guidelines, to at least ensure minimum acceptable methodological standards, may create uncertainty about the value of these data and risk the imposition of such requirements on providers by external authorities. It is therefore essential that the NHS provides a central unit for the coordination of cost-effectiveness and quality of life data. Such a unit might also serve as a means of dissemination and guidance to General Practitioners (GPs).

3.11 **We recommend that the Health Department initiate a dialogue with the pharmaceutical/health care industries with the objective of further developing and agreeing common and validated methodology for assessing the economic and quality of life data assembled to support individual products. Professional groups should then be identified within the health service who could, with appropriate training, assume responsibility for receiving, assessing and disseminating this data.**

ACTION
Health Departments and pharmaceutical/health care industries to develop and agree common and validated methodologies for economic assessment.

Good clinical practice

3.12 One of the UK's successes in the area of assessment and evaluation is the clinical research interface for pharmaceuticals. International companies therefore choose to conduct a significant proportion of their clinical research in the UK. However, if this success is to continue there has to be an increased understanding and use of Good Clinical Practice (note 4). Industry depends on high quality work which is compatible and suitable for international regulatory purposes in general and European Community (EC) Guidelines in particular.

The lack of understanding of Good Clinical Practice (GCP) by some UK doctors and their failure to adhere to both the principles and associated documentary practices of GCP can reduce the value of clinical trials data generated in the UK. British medicine is competing in an international market place for pharmaceutical industry resources and must generate data efficiently to continue as a preferred partner. Internationally recognised trials will also lead to earlier availability of useful new medicines for patients. Funding should be provided by government and the research based pharmaceutical/health care industries.

3.13 **We recommend that the NHS should coordinate, after appropriate discussions, the introduction of GCP training programmes for clinicians and scientists involved in the design, execution and reporting of clinical research studies.**

ACTION
NHS to introduce GCP training programmes.

4 IMPLEMENTATION

Scientist/clinician interface

4.1 The major organisation in the health service at the interface between research and its application to clinical practice is the teaching hospital. It is in teaching hospitals and then in associated medical schools and research institutes that the opportunities to apply research to practice most commonly arise. However, considerable difficulty is experienced bringing about transfer from research to practice and a considerable 'grey area' exists between the stage when the work is the unequivocal responsibility of the research agency, eg research council or medical charity, and the step when its clinical utility is proven and it becomes a necessary and undeniable responsibility of the hospital.

The problem is most evident in relation to medical equipment but also occurs in various other areas, eg in diagnostic assays which are originally developed as part of research projects. The existence of this gap is a major weakness of teaching hospitals and reflects a system in which funds for technology transfer are not specifically identifiable within teaching hospitals' budgets. It is hoped that this is a problem that can be addressed as part of the current review of Service Increment for Teaching and Research (SIFTR) funding mechanisms.

Dissemination of information

4.2 After effective assessment and to ensure value for money, the handling, implementation and dissemination of information must be efficient and controlled. The NHS is generally perceived by its suppliers as a customer that lacks effective internal systems to coordinate information about product performance and identify future needs. The evolution of NHS Trusts is likely to lead to the isolation of service providers unless mechanisms are established to disseminate knowledge about new technologies and their efficacy.

4.3 **We recommend that the NHS Supplies Authority and the Health Departments should take immediate steps to improve the rate at which useful information about product performance is fed back to suppliers recognising that such evaluation is very valuable both to users within the service and to competitive suppliers seeking to improve their product range.**

ACTION
NHS Supplies Authority to improve the rate and quality of feedback to suppliers.

Adoption and diffusion

4.4 The implementation of developments in the UK is a very haphazard process. When it concerns equipment which can be added on to practice without fundamental changes, adoption is often very uncritical. On the other hand some practices which have been proven to be effective, even cost-effective, are very slowly adopted, eg day case surgery.

There is evidence that some clinicians continue to use certain protocols even when others have been demonstrated to be more effective in terms of outcome. It cannot be assumed that the rapid dissemination of assessments and evaluation will lead to national implementation of successful advances.

4.5 Aside from removal of particular blocks or disincentives which result in medical practices not being adopted or stopped, a wider implementation strategy will often be required which would include influencing consumers, professionals, managers and policy makers. All of us, though, are most influenced by people not paper, so using patients' influence and professional opinion leaders might be most effective. This might be a suitable remit for the group of regional R&D directors.

4.6 **We recommend that the NHS, through its regional R&D directors, establish communication channels aimed at the scientist/clinician interface to ensure that validated procedures are effectively implemented and outdated techniques are supplanted. Any implementation programme must be underpinned by monitoring of adoption and uptake.**

ACTION
NHS to establish implementation and monitoring programme.

Public health screening

4.7 The recent White Paper *The Health of the Nation* emphasised the importance of preventive medicine and the need for early detection and timely interventions if an effective remedy is available. To achieve this will require central direction and funding to ensure that there are appropriate structures to enable worthwhile innovations to be adopted nationally and applied cost-effectively.

In response to these considerations the present Committee singled out public health screening for specific examination; this is summarised in Appendix B.

4.8 There is clear evidence that some tests are of considerable value but are not properly, or cost-effectively, implemented. An example is screening for cervical cancer. A national screening programme achieving the full potential reduction in mortality would need no more than about three million cervical smear examinations a year, with each woman aged 25-64 tested at about five yearly intervals. In fact over five million smear tests are performed each year and the programme has achieved a disappointingly low reduction in mortality. Young women, at low risk, may receive yearly smear tests, whereas until recently most older women, at high risk, were not offered smear tests.

Despite national guidelines, screening policy is determined locally and the service is not unified; there is waste and a lack of equity. Each individual should have an equal opportunity to benefit from a screening procedure regardless of social and financial circumstances.

A further lost opportunity is screening for diabetic retinopathy. Research has shown that screening for early diabetic retinopathy with prompt laser photo-coagulation treatment can prevent blindness. An effective screening method is thus languishing because of a lack of national policy and a health service development initiative.

4.9 Conversely, screening and diagnostic tests have been introduced into practice before their effectiveness in preventing morbidity and death has been satisfactorily quantified and balanced against the costs. For example ultrasound ovarian scanning can detect early cancer but there is no evidence to show that this will lead to a reduction in morbidity or mortality.

If this necessary research is not done before a test becomes accepted in clinical practice it may never be done. The need for quantitative appraisals of screening is widely acknowledged but inadequately adopted. As a result, some ineffective tests are widely used, some cost-effective tests are inappropriately used, and other tests are used despite the lack of any assessment of their value. There is no adequate mechanism for the controlled implementation of novel tests.

A nationally directed programme for public health screening has the potential for major improvements in cost-effectiveness.

4.10 **We recommend**
(i) the NHS establishes a major initiative to ensure screening research directs national policy formulation.
(ii) the NHS should also develop a mechanism for the national implementation of public screening services to ensure that cost-effective screening programmes are available to the public throughout the national health service.
(iii) consideration needs to be given to how existing screening services could be more effectively integrated into a national programme.

ACTION
NHS to use screening research to direct national policy formulation, and to subsequently develop mechanisms for implementation of an intergrated national strategy.

Organ transplantation

4.11 Through progress in surgical techniques, reinforced by the development of effective immunosuppressants and antibiotics, effective transplantation of organs (kidney, hearts, liver, cornea) and cells (bone marrow) over the past forty years has been a major achievement of 20th century medicine.

Kidney transplantation is now the treatment of choice for end-stage renal failure, and bone marrow transplantation has become the preferred treatment for some forms of leukaemia and marrow aplasia.

Apart from bone marrow transplantation, cellular transplantation is a relatively new concept but is likely to have an important role in the future as growth factors and new knowledge of cellular biology allow specialised cells to be grown and manipulated in vitro by genetic modification.

4.12 Although the technologies are available, the full benefits to patients which can be achieved are not being realised because of a shortage of organs for transplantation. While the number of transplants in the first half of 1992 significantly exceeded that in the same period of 1991, less than one fifth of possible recipients received kidney transplants. Since past measures to increase organ supply have failed, radical actions need to be considered.

4.13 **We recommend therefore that the health departments enhance the number of organs available and investigate mechanisms to introduce an opt-out system similar to those operated in Belgium, France and Austria.**

ACTION
Health Departments to introduce an opt-out system for organ donation.

5 SUMMARY OF PRINCIPAL ACTIONS

ISSUE	OBJECTIVES	INITIATOR	POSSIBLE COLLABORATORS	TEXT REFERENCE
• the development gap	establish MEDILINK	DTI	Health Departments NHS	2.2 — 2.6
• intellectual property rights (IPR)	provide training on IPR	HEIs	NHS Research Councils ABPI ABHI	2.7 — 2.8
• period of grace	harmonisation of US and EC IPR	Patent Offices	-	2.9 — 2.10
• health technology assessment	development under controlled conditions	NHS	Health Departments Research Councils Medical Charities Royal Colleges ABHI	3.1 — 3.5
• assessment of surgical procedures	establish committee on Safety and Efficacy of Procedures	Health Departments	NHS Research Councils Medical Charities Royal Colleges ABHI	3.6 — 3.8
• health economics	develop and validate methodology for assessing economic a quality of life data	Health Departments	ABHI ABPI	3.9 — 3.11
• good clinical practice	introduce training programme on GCP	NHS	Research Councils Medical charities ABPI	3.12 — 3.13
• product database	improve rate and quality of feedback about product performance	NHS	Health Departments ABHI	4.2 — 4.3
• implementation	establish implementation and monitoring programme	NHS	Health Departments Research Councils Medical Charities	4.4 — 4.6
• screening	use screening research to direct national policy; develop mechanism for implementation and integration	NHS	Health departments MRC Medical Charities Royal Colleges	4.7 — 4.10
• organ transplantation	introduce opt-out system	Health Departments	ethic committees	4.11 — 4.13

6 CONCLUSION

Invitation to action

Medical research and health issues have been and are currently the subject of many studies. Nevertheless by concentrating on a particular aspect of the innovation process the Committee was able to highlight specific issues which are in tune with the aims of the recent White Paper to promote health and treat ill health.

Progress in revolutionising the health and health care of the British people depends on effective health education, adequate health care infrastructures and comprehensive public health approaches. There is no doubt that if successful partnerships between academia/industry/NHS reach their potential, for example by developing anti cancer drugs or vaccines capable of preventing HIV, the future benefits in quality of life will be significant.

Whatever policy position is adopted to address the issues, influencing the effective transfer of medical advances into patient care must reflect a community of purpose and a recognition of responsibility across government departments, health professionals, industry and the public.

The emphasis throughout the study has been to produce a small number of significant recommendations to ensure a high degree of action. A number of the recommendations are of general applicability; however they are especially important in medical and health care because of the social and economic impact on the UK. Others have a specific focus eg those related to surgical procedures, Medilink, public health screening, and organ donation.

The Committee deliberately chose to exclude education and training as a subject for one of its task forces since expert committees such as that chaired by Professor Colin Campbell are focusing specifically on the special nature of these issues. However, given the complex nature of the technology transfer process and the role of the health service teaching hospitals and research councils, the importance of education and training featured prominently in every discussion.

The recent publication of an NHS R&D strategy for England is a major step forward and together with the mechanisms developed in the rest of the UK should, if adequately resourced, provide the means of implementing some of the principal recommendations proposed in this report.

ACOST intend to follow up its recommendations in 12 months to chart progress made.

Some of the recommendations will need radical change to existing mechanisms and will stimulate ethical debate. However, decisive action is necessary, if the benefits of the nation's massive investment in medical R&D is to be translated more effectively into improvements in health care.

7 TASK FORCE CONCLUSIONS

Five task forces were set up by the Medical Research and Health committee to consider particular medical advances and how effectively they had been transferred to patient care. Their reports were presented to the Committee as input for discussion and the conclusions are summarised here.

The Committee believes that the task forces' reports contain valuable information and specialist views, which might have wider interest and relevance. Whilst the Committee has agreed to publish these reports as background information, it should be pointed out that the task forces conclusions may not be identical to the final conclusions and recommendations of the Committee when all of the evidence had been considered.

7.1 Pharmaceuticals

7.1.1 With a record trade surplus of £1,100m reported in 1990, the UK pharmaceutical industry was the third largest positive contributor to the nation's balance of trade, after the power generating machinery industry and the petroleum industry. Very few British industries today match the consistent performance of the pharmaceutical industry. Its success to date has been based on the development of small molecules as drugs; it therefore owes much to the past strength of organic chemistry in the UK. The key issues identified by the task force therefore reflected recognition of the past successes of the pharmaceutical industry and focused on the importance of ensuring future achievements.

Molecular biology will offer additional ways, through protein engineering, of designing small molecule drugs; for example by using the three dimensional structure of receptors. It is therefore essential that the UK maintains a sound academic research base to provide a suitable cadre of graduates and to act as a stimulus for industry which in turn has to resource and support the science base. We encourage the recent initiatives taken by OST and DTI to identify generic and emerging technologies with the aim of supporting some strategic research programmes.

7.1.2 The paucity of active venture groups in R&D based biotechnology/health care in the UK is related to the lack of an efficient exit route. In the USA the National Association of Securities Dealers (USA) Quotations (NASDAQ) exchange allows biotechnology/pharmaceutical type ventures to obtain a listing, and therefore further funding, at a very early stage in the companies development. The availability of this exit route has encouraged the proliferation of venture funds prepared to invest in biomedical R&D. **We therefore recommend that the Stock Exchange should investigate a mechanism to address this issue.**

7.1.3 It is clear that universities and industry have complementary roles to play. The transfer of pharmaceutical advances from laboratory to clinical research depends on the provision of a cadre of appropriately trained clinical and nonclinical scientists. We welcome the initiatives taken by several of the major UK pharmaceutical companies to provide 'sandwich' course options and vacation employment thus enabling young undergraduates to be exposed to R&D at the earliest opportunity.

We recommend that the Committee of Vice-Chancellors and Principals (CVCP) and the HEFCs consider extending these opportunities subject to the availability of suitable industrial placements.

The MRC should discuss with the ABPI and the UK Patent Marketing Department, the possibility of designing and undertaking to provide a training course for biomedical undergraduates and scientists in the importance and evaluation of intellectual property.

7.1.4 We wish to encourage greater interaction between universities and industry and **recommend that the HEFCs and research councils consider encouraging industry to second researchers and senior managers to joint university - led research programmes.**

We also recommend that the CVCP and the HEFCs facilitate arrangements whereby joint appointments in industry and academia can be taken up. Existing but isolated examples have demonstrated the value of this approach.

Whilst some UK companies are effective at receiving and evaluating third party opportunities this is not uniformly the case. **We recommend that UK companies should be encouraged to upgrade their resources in this area of technology transfer.**

7.1.5 We support the efforts being made internationally to harmonise patent regulations. The pressure on scientists to publish their research quickly has restricted the interaction between academia and industry. **The Government should therefore encourage the National Patent Office and the European Patent Office to allow publication of a discovery with protection of IPR, provided a patent is filed within twelve months after publication. This legislation is successful in the USA.**

7.1.6 The lack of understanding of GCP by many UK doctors and their failure to adhere to both the principles and associated documentary practices of GCP can reduce the value of clinical trials data generated in the UK. British medicine is competing in an international market place for pharmaceutical industry resources and must generate reliable data efficiently to continue as a preferred partner. Internationally recognised trials will also lead to earlier availability of useful new medicines for patients.

The NHS should liaise with the Universities, Research Councils and the Health Departments to introduce GCP training programmes for doctors and scientists involved in the design, execution and reporting of clinical research studies. Funding should be considered both from these bodies and the research based pharmaceutical industry.

7.1.7 The understanding of economic and quality of life assessments of medicines within the NHS is limited and this impedes the communication of such information between providers (pharmaceutical manufacturers) and the potential users of economic evaluation data. **The Health Departments should therefore initiate a dialogue with the pharmaceutical industry with the objective of identifying professional groups within the service who could, with appropriate training, assume responsibility for receiving and assessing the economic and quality**

of life data, assembled to support individual pharmaceutical products. Innovations which are recognised as offering significant economic and/or quality of life advantages should be fully funded under the NHS.

7.2 Gene therapy and transplantation

7.2.1 Gene therapy for a variety of diseases is now a medical reality. Several procedures have already been carried out in the USA at the NIH. In the UK, the Clothier Committee have recently published guidelines on the practical and ethical issues of gene therapy.

7.2.2 The scope and opportunities for research and applications in gene therapy and transplantation are huge, ranging from correcting single gene defects to the correction by gene therapy of somatic genetic changes that underlie the common cancers. The burden and cost to the NHS of genetic diseases justifies action by **the Health Departments who should set up workshops to form links between academia/ medical charities/research councils/NHS with the aim of providing a database and focus for the early development of cost-effective advances.**

A major step in this direction has already been taken by the MRC with its initiative on the genetic approach to human health. A Steering Committee has been set up by the MRC to oversee the initiative, to channel genetics research towards the improvement of human health and to advise on priorities for investment.

7.2.3 It seems likely that a number of groups in the UK will wish to explore gene therapy within the next year or two. However, there will be a number of requirements which are almost certainly beyond the scope of most basic and clinical research laboratories in medical schools and research institutes. It will be necessary to prepare cells in sufficient quantities and to carry out initial separation steps before transfection with appropriate retroviral or other virus vectors is initiated. It will be essential to monitor the safety at each stage and to carry out all procedures according to the guidelines for Good Manufacturing Practice. This will therefore require expertise in the handling of cells, the construction of vectors, and a sophisticated knowledge of retrovirology and other virus vectors with particular respect to safety aspects.

We believe that the infrastructures and some technical expertise is already available within the blood transfusion service (BTS). **The BTS, with appropriate external advice should assess the requirements and resources needed to develop advances in gene therapy and transplantation. They might subsequently wish to consider building up one or two centres to take forward these developments.**

7.2.4 The Health Departments in collaboration with the HEIs and the NHS should ensure that technology transfer arrangements are adequately set up to advance and develop research from NHS hospitals. In view of the complexity of technology transfer the CVCP and the HEFCs should consider whether industrial liaison directors who generally support entire university research programmes should be encouraged to develop specialisation, possibly at designated centres. These Liaison Centres might work under agency status and could additionally have access to a central development fund to which applications for support could be made. The fund could aim to be self-financing calling on a small percentage of the exploitation

revenues of its borrowers to re-invest in future projects. The Health Departments R&D division should also consider how large scale clinical trials might be resourced.

7.3 Surgery

7.3.1 The task force addressed the therapeutic use, rather than diagnostic application, of minimal access surgery*. Minimal access surgery was made possible by the development of fibreoptics in the 1950s. The ability to transmit intense light from its source to the point of action through flexible fiberoptic bundles, combined with the manufacture of small flexible instruments has enabled medical practitioners to work inside the body either through natural orifices or through small holes made into the body. The most recent addition to the technology has been small cameras able to produce high quality magnified images on screens. Ideas for subsequent applications came primarily from industry but there was also a strong surgical input. The availability of technology has resulted in a search for medical applications as opposed to medical problems driving the development of technology. There has been an explosion of interest in the techniques involved in minimal access surgery and a correspondingly rapid increase in its use.

7.3.2 The available evidence indicates that although it is a relatively new therapeutic technique, minimal access surgery might offer real benefits on the cost and quality of care in an increasing range of applications. Its development and adoption has in many cases been rapid although often haphazard, resulting in some cases in uncritical take up and uncoordinated introduction with a less than effective return to the NHS. The increasing number of negative reports (mainly concerned with overuse of the procedures) emphasises the need for early action to introduce formal assessment procedures.

7.3.3 If a novel development is to be promoted for general use it is essential that it should undergo scientific surgical assessment including evaluating safety, efficacy, outcomes in the short and long-term (including comparisons with existing alternatives) cost-effectiveness and indications for use. There are no dedicated facilities in the UK to carry out these assessments in any systematic way. The lack of effective and efficient information systems has inhibited the gathering and evaluation of both national and international assessment data.

7.3.4 **The NHS should require all new medical devices or novel applications of existing devices to be developed only under controlled conditions**. This would include using protocols where optimal appropriate assessment can take place to ensure that the procedures are shown to be medically acceptable for general use. The recent EC legislation to regulate standards for commercially available active implantable medical devices is welcome as are the proposals to extend the legislation to other medical devices by 1995.

* *A surgical procedure can be divided into three stages. Firstly there is incision into the body, secondly removal or repair of an organ or tissue and lastly closure of the incision. In minimal access surgery the major impact of the procedure is on the first and last stages. There are only one or more small incisions of less than one and a half centimetres, and patient trauma, post operative pain and metabolic sequelae are reduced. However, advances in instrumentation, which have developed as the procedures have been applied, are now resulting in changes in the removal and repair procedures.*

7.3.5 **The assessment procedure detailed above should also involve assessment of the cost-effectiveness of the new device or novel procedure**. Those which offered significant patient benefits should then be given priority funding from DH to facilitate their implementation into the NHS.

7.3.6 **Until the proposed European licensing procedures are introduced the NHS should be responsible for ensuring that only procedures and equipment which have undergone assessment and approval are used**. After the initial investigation and assessment phase has provided a firm base for the more routine use of a device or procedure, **the Royal Colleges in collaboration with the NHS should produce codes of practice covering the training of surgeons**. Surgical training in the future is likely to increasingly include the use of computer-aided teaching packages and simulators. It is clear that the resources to facilitate the use of these will have to be found.

7.3.7 **Novel surgical procedures and surgical teams should be registered with a Committee on the Safety and Efficacy of Procedures**. It should be compulsory to provide effectiveness and quality control data on new procedure which could be recorded and analysed at independent assessment units and be made publicly available, possibly through the Regional Health Authorities, who might also have a role in overseeing evaluation and introduction. This would introduce some control over the introduction of novel techniques and establish a data-collection and handling centre which could be linked to the NHS registry. The present lack of adequate records of patient treatments and outcomes makes objective assessment of the merits of novel procedures more difficult. There is a useful model procedure for monitoring untoward incidents which is carried out by the Medical Defence Union as part of their health care risk management programme. The reporting system is not widespread but has been successful and effective in the centres where it has been established.

7.3.8 **The NHS should follow the codes of practice in deciding the most cost-effective way of introducing novel devices/applications**. The appointment of consultants to undertake these procedures and the provision of equipment and facilities should be based on an analysis of the pattern of service best able to meet the needs and preferences of the population. **The NHS in consultation with the Royal Colleges should identify teaching hospitals specialising in appropriate diseases and techniques and provide these units with resources to act as task forces to develop, evaluate and educate the rest of the profession.**

7.4 Medical devices

7.4.1 The Advisory Council on Applied Research and Development (ACARD) report on medical equipment published in 1986 made a number of recommendations about medical equipment technology transfer (Appendix A). The task force strongly supported these recommendations and expressed concern about the ineffective implementation of the recommendations by Government.

7.4.2 The importance of the NHS influence on the UK medical equipment industry was recognised by ACARD. UK companies have to compete internationally to remain successful. However, competitive suppliers can gain from interactions with a wellinformed and demanding customer particularly in their home market. To

be able to sell overseas it is vital to demonstrate that the product has been accepted in the home market place (or in the United States). **The NHS should review these concepts ensuring maximum benefits accrue to the NHS from any purchasing agreements.**

7.4.3 There is a need to improve the two-way flow of information between inventors and investors about technical and market opportunities. This applies particularly to emergent or neglected areas of health care, such as community care and the support of informal carers. The task force discussed at length the need for more effective technology-broking in relation to medical devices, to assist inventors and to speed the sourcing of relevant technology.

7.4.4 The Centre for Exploitation of Science and Technology (CEST) conducted a study to look at schemes which would provide a 'safe place to talk' for inventors in need of rapid commercial assessment of product ideas. Some hospitals have established separate organisations to handle technology licensing and contract management. Caduceus at the Royal Postgraduate Medical School, London is one example, which handles development and evaluation contracts placed with research groups at the Hammersmith Hospital, London. These are almost exclusively in pharmaceuticals. Isis Innovation in Oxford plays a similar role, although it is not limited to medical research and is primarily involved in licensing. It is wholly-owned by Oxford University and plays a complementary role to that of the Industrial Liaison Office. In some cases the inventor may wish to set up a business rather than license the technology. Isis Innovation has assisted the formation of several science-based companies by university researchers, including Oxford Molecular Ltd, which markets computer software for molecular modelling and Fungal Controls which sells novel fungicides. A variant is to be found at University College, London,(UCL) which also has a Liaison Unit. This is UCL Ventures, which is intended to assist employees of the college start their own businesses on campus.

Another possibility is the Innovation Notice Board at the Design Council, which was set up after the Toshiba Year of Invention design competition revealed that a significant proportion (10 per cent of around 4000 entries) of the exploitable ideas submitted to the scheme remained unexploited. An Assessment Committee meets monthly to review around 15 to 20 selected product ideas. Those that are considered technically and commercially interesting by outside experts and the members of the Assessment Committee are then circulated to companies who pay a subscription of £60 which entitles them to receive proposals relevant to their business.

Somewhat similar is the work of the Institute of Patentees and Inventors, which offers a confidential advisory service to subscribers. Around 100 proposals per year receive a formal assessment. Six licensing organisations, including British Technology Group, provide financial support to the Institute and receive information about the most interesting proposals. In effect they thereby contract out some screening of ideas and provision of basic advice on IPR and market potential. This in itself suggests that there are very low returns from providing a safe place to talk and that it is best done as an adjunct to institutionally advisory services such as those considered above. Nonetheless, some product development consultants do offer advisory services to inventors and effect introduction to product developers and investors. Some of them have come together to form the Association for Innovation Management to promulgate a code of practice for this activity.

7.4.5 We note the recent transfer of the Co-ordinating Group on Medical Devices into a research liaison committee on biomedical technology and welcome its revised remit. However, we recognise that a division within the Innovation Unit of the DTI would be better placed to co-ordinate the activities of government departments, research councils, charities and industry in developing medical equipment. The DTI division should examine how funding can be directed to bridge the development gap and finance prototype development and demonstrator projects. An extension of LINK, Support for Product Under Research (SPUR) or Small Firms Merit Award for Research and Technology (SMART) might be considered.

We recommend that the DTI establish a new division possibly within the Innovation Unit specifically charged to co-ordinate the activities of government departments, research councils, charities and industry in developing medical equipment.

7.4.6 The NHS is generally perceived by its suppliers as a customer that lacks effective internal systems to co-ordinate information about future product needs. Measures are urgently needed to transform the NHS into an 'intelligent customer', of a kind well established in retailing.

7.4.7 We welcome the DTI's recent launch of The Senior Academics in Industry Programme. However, longer-term ties and structural changes enabling periodic movement from industry to academia and *vice versa* would also improve technology transfer. **The R&D divisions of the Health Departments should seek to establish Centres for Medical Technology modelled on the unit created at University College London and take industrial advice on an appropriate mode of operation.**

7.4.8 It is a substantial handicap for UK companies, when promoting a new product, to admit that it not being used in their home market. **The NHS should urgently review the 'pump-priming' concept with the NHS committed to purchase significant quantities of products, emerging from the Health Departments/ NHS directed R & D programmes, which achieve predetermined clinical objectives.**

7.4.9 **The NHS should change the conditions of service of their staff to permit them to act as consultants to industry to assist in the process of Technology Transfer on condition that individuals declare an interest when purchasing decisions are being taken**. Industry would also benefit from more job interchange on a temporary basis with the NHS.

7.4.10 Proactive involvement in the EC is vital. **The Government should increase funding to support participation by UK scientists and engineers in European and International Standardisation committees and discussion panels.**

Appendix A: Summary of ACARD recommendations on medical equipment

A NHS decision makers should be kept constantly aware that NHS purchasing is by far the dominant domestic influence on the shape of the UK medical equipment industry, and that the NHS benefits both directly and indirectly from a healthy UK industry. We recommend that the Health Departments should issue guidance emphasising the need for a full option appraisal, including full consideration of British equipment and making use of the available expert advice, for all major NHS purchases, whether or not they are financed from public funds.

B NHS decision makers need stronger support in terms of systems, information, and expertise. The new NHS Director of Procurement and Distribution should continue the process of improving NHS information, financial, and purchasing systems as rapidly as possible. The DHSS should take steps to provide for increased research and information on the health economics of new techniques and equipment. Health Authorities should be encouraged to invest in new equipment where this can be shown to offer increased efficiency, and the economic appraisal expertise available to Health Authorities should be strengthened. The DH/SHHD evaluation programme should be continued and expanded, and the modest expenditure devoted to it should be materially increased. The 'pump-priming' funds available to the DHSS should be used primarily to introduce new medical technologies of British manufacture to the NHS and to promote their rapid assessment.

C The capital equipment provision in both Regional and District Health Authority budgets should be increased, and steps should be taken to ensure that this provision is used for the purpose for which it was allocated.

D The market for equipment in the primary health care sector is growing rapidly outside this country. In considering policy on the funding of primary health care services, the Government should take into account the interest of the medical equipment industry in a GP market parallel to that existing elsewhere. Trial practices should be established in which GPs would be encouraged to provide a greater range of services, and UK industry should be linked with this experiment and encouraged to use these practices as a test ground for new products aimed at the GP market.

E Government support for R&D on medical equipment should be substantially increased. A mechanism should be set up to co-ordinate the programmes of DHSS, DTI and SERC in the medical equipment field. This mechanism should involve participation by MRC and industry.

F The industry needs to address international markets, and there are several steps the Government could take to help it to do so. The regulatory environment is particularly important. Additional manpower should be provided to STB for the operation and expansion of the Manufacturer Registration Scheme. The Government should take a stronger political initiative within the EC to create a freer internal market in medical equipment by eliminating the barriers currently created by differing national standards and regulatory regimes. The Government should recognise the value to UK industry of overseas students studying medicine and its supporting disciplines here, and in particular should give positive encouragement to postgraduate study in the UK in these. DTI should give wider publicity to market reports from British Posts overseas and to the other help to exporters which Posts can provide.

G A single Branch within DTI should be given co-ordinating responsibility for all those sponsorship and support activities towards the medical equipment industry that fall to DTI, including responsibility for liaison with DHSS and SERC on matters relating to the industry.

H We found perceived barriers to the essential close collaboration between the industry and members of the health care professions, and make recommendations to overcome them. The Health Departments should issue new guidance to Health Authorities which, while reiterating the need to prevent corruption in purchasing activities, gives positive encouragement to the creation of R&D links with UK-based firms. They should also issue guidance on the terms of relationships with firms, and should encourage Health Authorities to employ staff on contracts which permit them, if they wish, to spend part of their time in industry. The Health Departments, the main trade associations and those professional associations which are active in this field should take steps to improve understanding between people in industry and those in the health service.

I The industry could also derive greater benefit from the education and training system, SERC should give high priority to medical engineering in their support of postgraduate training. Medical engineering, industrial design, and management engineering should be priority areas for future university appointments.

J There are problems in obtaining good and relevant statistical and market data on the industry. A joint group from industry, Customs and Excise and DTI should be set up to produce a more helpful classification scheme for the government statistics relating to the industry. The NHS should begin now to plan how its equipment purchasing data could be made available to industry.

7.5 Screening, diagnosis and prevention

7.5.1 For the purpose of the study, consideration of screening and preventive procedures was restricted to activities that relied on direct medical intervention, and did not include assessment of the value of improved living standards, lifestyle changes (such as diet and smoking) or immunisation. Screening was defined as the application of a test or procedure used to identify, among apparently healthy individuals, those who were at sufficiently high risk of a specific disorder, to benefit from a subsequent diagnostic test or procedure or in certain circumstances direct preventive action. A summary of the case studies considered by the task force is at Appendix B.

7.5.2 Screening and diagnostic tests have been introduced into practice before their effectiveness in preventing morbidity and death has been satisfactorily quantified and balanced against the costs. If this necessary research is not done before a test becomes accepted in clinical practice it may never be done. The need for quantitative appraisals of screening is widely acknowledged but inadequately adopted.
As a result, some ineffective tests are widely used, some cost-effective tests are inappropriately used, and other tests are used despite the lack of any assessment of their value. There is no adequate mechanism for the controlled implementation of novel tests. The task force discussed and reported examples of each of these categories.

7.5.3 Some tests are of considerable value but are not properly, or cost-effectively, implemented. An example is screening for cervical cancer. A national screening programme achieving the full potential reduction in mortality would need no more than about three million cervical smear examinations a year, with each woman aged 25-64 tested at about five yearly intervals. In fact over five million smear tests are performed each year and the programme has achieved a disappointingly low reduction in mortality. Young women, at low risk, may receive yearly smear tests, whereas until recently most older women, at high risk, were not offered smear tests. Despite national guidelines, screening policy is determined locally and the service is not unified; there is waste and a lack of equity. Each individual should have an equal opportunity to benefit from a screening procedure regardless of social and financial circumstances. A nationally directed programme has the potential for major improvements in cost-effectiveness.

7.5.4 Some tests are of value but are novel and need a mechanism for controlled implementation. Serum screening for Down's Syndrome for example can now detect over 60 per cent of affected pregnancies and its effective implementation would have more impact than any other in reducing the prevalence of severe mental retardation. However, it has proved extremely difficult to obtain funding to launch pilot screening programmes and each Health District is embarking on fresh discussions on whether to implement such screening and, if so, how. This is without doubt a service that could be discussed at national level and offered to all pregnant women on a consistent and equitable basis. There is an urgent need for an organisation with the responsibility and resources to fund and implement such screening. Antenatal screening for cystic fibrosis is another example where the responsibility for funding and implementing the necessary pilot programmes has fallen between two stools.

7.5.5 **The task force recommend that the NHS realign its existing resources into a public health screening service to ensure that high quality screening programmes are available to the public throughout the national health service. These services would be co-ordinated by a central screening authority.**

7.5.6 The task force considered that the organisation and funding of research into screening had been a problematic area that required a special solution. It was felt that research into screening should not be the preserve of any one organisation. Complementary contributions could be made from the universities, research councils, health service charities and industry. However, there was a need to maintain a database of screening research, co-ordinate research activities and avoid duplication. A public health screening service should also have a R&D function and develop a network of collaborative projects with the appropriate specialist groups. Until such a Service were set up there is an urgent need for the MRC to take on the main responsibility for sponsoring screening research in Britain. It may even continue to be the main sponsor after such a service has been set up. **We recommend that the MRC Epidemiological and Prevention Board take responsibility for sponsoring screening research.**

7.5.7 **The new Epidemiological and Preventive Medicine Board of the MRC should redirect existing fellowships towards the quantitative appraisal of screening technologies**. Appropriate university departments, especially those in community medicine, should also review whether their academic cover of screening is satisfactory. The R&D arm of the NHS should be encouraged to accept a role in training medical staff in aspects of screening.

Appendix B: Screening in the UK. Points from illustrative case studies—from research to practice.

		RESEARCH AND QUANTITATIVE ASSESSMENT	DEVELOPMENT
ANTENATAL AND NEONATAL SCREENING	Neural Tube Defects	Satisfactory sensitivity, specificity, cost and benefits assessed before implementation	Fair, but poorly co-ordinated
	Down's Syndrome	Satisfactory sensitivity specificity, cost and benefits assessed before implementation.	Poor - lack of strategy and funding.
	Cystic Fibrosis	Identification of CF gene and main mutations offers prospects for screening; several screening approaches possible.	Poor - lack of mechanism to review screening implementation or mechanism for novel implementation.
	Toxoplasmosis	Tests available but uncertainty of their utility. Research needed to assess practical health benefits.	-
	Neonatal haemoglobinopathy screening	Test available and samples already collected. Need to avoid simple extension of testing.	Quantitative appraisals for specific haemoglobinopathies needed. Development of policy needed.
CANCER	Prostate	Uncontrolled clinical data available on ultrasound, digital rectal examination and prostate specific antigen. Need for a formal review of screening potential and research needs.	-
CARDIO-VASCULAR DISEASE	Coronary Heart Disease (CHD)	Much information on serum cholesterol as a risk factor for CHD. Inadequate quantitative appraisal of serum cholesterol as a screening test, either alone or in combination with other lipoprotein measurement, blood pressure and smoking.	Inappropriate developments in view of lack of evidence of screening value.
	Cerebrovascular disease	Much information on blood pressure as a risk factor for cerebrovascular disease. Inadequate quantitative appraisal as a screening test. Screening is effective but lack of clear national screening policy.	Developments need to await agreement on appropriate national screening policy.

IMPLEMENTATION	MONITORING AND EVALUATION	COLLABORATION WITH INDUSTRY	CONCLUSION
Ad Hoc introduction in different districts. Some districts have no service—lack of equity. Long introduction greater than 15 years.	Inadequate. No national system other than birth defect notifications	Poor, both with respect to diagnostics and ultrasound.	An effective screening method, introduced piece-meal, no central direction.
Repetition of experience with neural tube defects. No mechanism for controlled introduction.	Inadequate Initiative based on national Down's Syndrome registar needs support and placed with a responsible authority.	Poor - some joint initiatives but limited and inefficient.	An effective screening method in a state of development that requires a national policy for implementation and monitoring.
Too early for national policy. Urgent need for demonstration projects to identify most cost-effective method of screening. Lack of commitment by funding bodies to take on this responsibility.	No mechanism in place despite urgency.	Poor - with confusion of intellectual property rights regarding DNA testing methods.	A potentially effective screening method that requires further quantitative appraisal and controlled screening programmes.
Inspite of lack of information on value such screening has been introduced in some countries with pressure to do so in UK.	-	-	A test of uncertain value that is liable to be introduced through pressure without proper evaluation. Need for research information.
Too soon but such screening offered in some places.	-	-	The technology and sample base tending to drive practice. A need for an appraisal.
-	-	-	Prostate screening being introduced on an **ad hoc** basis (systematically in some places such as Germany) without any evidence of efficacy. Urgent need for a formal assessment of research needs.
Haphazard	Non existent	-	Inappropriate and ill-conceived introduction of cholesterol screening for CHD. Need for formal quantitative appraisal using existing evidence to demonstrate poor value of screening.
GPs encouraged to measure blood pressure but lack of policy on age, sex, target groups, appropriate intervention strategies and expected health benefits of given strategy. Fragmented activity.	Non existent	-	Need for overview of screening options, development of policy with projected costs and benefits and national structure for implementing systematic screening.

Appendix B (continued): Screening in the UK. Points from illustrative case studies—from research to practice.

		RESEARCH AND QUANTITATIVE ASSESSMENT	DEVELOPMENT
BLINDNESS	Diabetic retinopathy	Excellent research has shown that screening for early diabetic retinopathy with prompt laser photo-coagulation treatment can prevent blindness. Quantitative appraisal performed.	Screening based on examination by optometrists shown to be feasible and acceptable.
CANCER	Cervix	Much biological work but **little early** quantitative assessments and no formal trial before service installed.	Little development work. Retrospective assessment of programmes yielding cost benefit estimates.
	Breast	Limited basic research; satisfactory quantitative appraisal; high quality randomised trials demonstrated efficacy of screening.	Satisfactory strategy but disagreement over who pays and lack of overall authority leading to difficulties in development programme.
	Colon and Rectum	Much work on faecal occult blood test endoscopy, satisfactory MRC trial of FOBT screening. Lack of overview of screening research needs.	No special need until value of screening has been shown.
	Ovary	Considerable work on ultrasound and tumour antigen measurement as possible screening tests. Failure to fund randomised trial; disagreement on responsibility for funding. Lack of appreciation of research needs.	No special need until value of screening has been shown.

IMPLEMENTATION	MONITORING AND EVALUATION	COLLABORATION WITH INDUSTRY	CONCLUSION
No national initiative. No register of diabetics to be called for eye examinations. No responsible authority taking up the tests.	Non existent	-	Effective screening method languishing because of alack of health service development initiative. No mechanism for policy development and initiation of national programme.
No central policy on screening strategy. No target population lists. Inadequate screening - treatment links. No managerial structure. Much waste.	Almost absent. Some evaluation conducted at district level and operational problems identified. Little impact on performance.	-	An effective screening method, introduced without proper evaluation and now implemented unsatisfactorily with weak management and wasted resources. Recent attempts to rectify problems.
Initial central funding and policy led to satisfactory launch. Target population identified. Management structure in place but still too decentralised - with unnecessary variations in practice.	Arrangement made through DH screening evaluation unit but difficulties because of lack of national database.	-	Many of problems with cervix cancer screening avoided but some remain, namely lack of central authority for service and development policy determined by local professional groups and lack of population database.
-	-	-	Satisfactory MRC randomised trial of faecal occult blood 'screening'. Need to evaluate the desirability of a trial of endoscopic methods.
-	-	-	Development research has demonstrated the potential of ultra-sound as a method of general population screening for ovarian cancer. The practical issues involved in mounting a randomized trial of such screening have not been satisfactorily dealt with.

ANNEX I

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ANNEX 2

Abbreviations

ABHI	=	Association of British Health-Care Industries
ABPI	=	Association of the British Pharmaceutical Industry
ACARD	=	Advisory Council on Applied Research and Development
BTS	=	Blood Transfusion Service
CEST	=	Centre for Exploitation of Science and Technology
CRADA	=	Cooperative Research and Development Agreement
CVCP	=	Committee of Vice-Chancellors and Principals
DES	=	Department of Education and Science
DH	=	Department of Health
DNA	=	Deoxyribonucleic Acid
DTI	=	Department of Trade and Industry
EC	=	European Community
ESRC	=	Economic and Social Research Council
GCP	=	Good Clinical Practice
GDP	=	Gross Domestic Product
GMC	=	General Medical Council
GP	=	General Practioners
HEFC	=	Higher Education Funding Council
HEI	=	Higher Education Institute
IPR	=	Intellectual Property Rights
ISS	=	Information Systems Strategy
MITI	=	Ministry of International Trade and Industry (Japan)
MRC	=	Medical Research Council
MRI	=	Magnetic resonance imaging
NASDAQ	=	National Association of Securities Dealers (USA) Quotations
NHS	=	National Health Service
NIH	=	National Institutes of Health
OECD	=	Organisation for Economic Co-operation and Development
R&D	=	Research and Development
SERC	=	Science and Engineering Research Council
SIFTR	=	Service Increment for Teaching and Research
SIRA	=	Scientific Instrument Research Association
SMART	=	Small firms Merit Award for Research and Technology
SPUR	=	Support for Product Under Research
UCL	=	University College London
UFC	=	Universities Funding Council

ANNEX 3

Notes

1 For the purpose of this study medical research was defined as basic research in the biomedical sciences and applied and clinical research into the causes and treatment of specific diseases. Health research was considered to be concerned with strategic and applied research concerned with the health needs of the community, including the provision of services to meet these needs.

2 Medical and health research in the UK is inherently multi-disciplinary and diverse. It has several main components, i) the Medical Research Council (MRC), the Economic and Social Research Council (ESRC) and to a lesser extent the other research councils; ii) the Higher Education Funding Councils (HEFCs); iii) the National Health Service (NHS); iv) the Health Departments; v) the medical research charities; vi) the pharmaceutical and medical equipment industries.

3 The OECD comprises some 24 countries including the countries of western Europe, Japan, the United States, Canada and Australia.

4 Good Clinical Practice encompasses a philosophy of clinical research to high scientific and ethical standards with an openness that allows or mandates others to review the work and, if necessary, assemble the raw data, analyse it and reach the same conclusions.

ANNEX 4

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Dr R Brook	*The Rand Corporation, USA*
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The Lord Butterfield	
Dr J Caddick	*IBM*
Professor D Campbell	*University of Glasgow*
Mr P Carlsson	*Centre for Medical Technology Assessment, University of Linkoping, Sweden*
Professor E R Carson	*City University*
Professor J Catford	*Health Promotion for Wales*
Mr T Chessells	*North East Thames Regional Health Authority*
Dr C Coles	*University of Southampton*
Ms H Dahlgren	*Swedish Council of Technology Assessment in Health Care, Stockholm, Sweden*
Dr G J Dempsey	*University of Ulster*
Dr A Dickens	*Commission of the European Communities, Brussels*
Mr O Edhag	*National Board of Health and Welfare,Stockholm, Sweden*
Mr K Ennefors	*Department of Health Care, Stockholm, Sweden*
Professor J Grimley Evans	*University of Oxford*
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Professor L Fine	*University College & Middlesex School of Medicine*
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Professor J Harrington	*University of Birmingham*
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J P R Herrmann	*Rothschild Asset Management Ltd*
Mr F Van Hoeck	*Commission of the European Communities, Brussels*
Professor W Holland	*Faculty of Public Health*
Professor P Howie	*University of Dundee*
Professor D J Hunter	*Nuffield Institute for Health Services Studies, University of Leeds*
Dr W J Hunter	*Commission of the European Communities, Brussels*
Dr D Jack	*Consultant*
Dr M Johnsson	*Karolinska Institute, Stockholm, Sweden*

Professor E Jonsson	*Swedish Council on Technology Assessment in Health Care, Stockholm, Sweden*
Ms P M Jonsson	*Swedish Planning and Rationalization Institute for the Health and Social Services, Stockholm, Sweden*
Mr I Karlberg	*General and Regional Hospitals, Stockholm, Sweden*
Dr S King	*Agency for Health Care Policy and Research, USA*
Professor J Lomas	*Dept. of Clinical Epidemiology and Biostatistics, McMaster University, Ontario, Canada*
Professor M Losowsky	*University of Leeds*
Professor D Marsden	*Institute of Neurology and National Hospitals for Nervous Diseases*
Professor J Marshall	*Institute of Ophthalmology*
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Ms I Petersson	*Department of Health Care, Stockholm, Sweden*
Professor C Pollitt	*Brunel University*
Professor P Porter	*Unilever Research, Colworth Laboratories*
Professor G Radda	*University of Oxford*
Mr R Rentoul	*University of London*
Mr J Robinson	*Smith & Nephew plc*
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Dr H Simon	*Schroder Ventures*
Ms E Thulin-Skantze	*Federation of County Councils, Stockholm, Sweden*
Professor G Stoddart	*Dept. of Clinical Epidemiology and Biostatistics, McMaster University Ontario, Canada*
Professor R W Stout	*Queen's University of Belfast*
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Professor E Symonas	*Department of Obstetrics & Gynaecology, University of Nottingham*
Professor J Tarn	*University of Liverpool*
Ms L Taylor	*Cambridge Health Authority*
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Professor L Werko	*Swedish Council on Technology Assessment in Health Care, Stockholm, Sweden*
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